



Procedural Sedation: Adult

Licensed Independent Practitioner (LIP)

Self-Learning Packet

Reference:

Swedish Procedural Sedation Committee

Updated December 2012

Procedural Sedation: Adult

LIP Self-Learning Packet (Online Version)

Dear LIP:

This is the self-paced learning module for moderate procedural sedation (MPS). If you have requested this privilege upon reappointment, please follow the directions below for approval. The documents and self-assessment referred to below are available at www.swedish.org/cme by clicking on the "Online CMEs" link. The direct link is: www.swedish.org/proceduralsedation.

Overview

Swedish Medical Center has a clinical procedure for *Procedural Sedation: Adult*. The purpose of this protocol is to provide management guidelines that ensure uniform care and consistent nursing practice for the adult patient receiving procedural sedation. The most recent version of the protocol can be found on Swedish On-Line in the Standards section.

Learning Objectives

At the conclusion of this course, participants will be able to provide better patient care through an increased ability to:

- Prepare and evaluate the patients prior to sedation
- Distinguish between the different levels of sedation and recognize when a patient's level of sedation progresses from moderate to deep
- Identify the drugs commonly administered to induce moderate procedural sedation
- Manage side effects and complications of moderate procedural sedation

Participant Instructions

- Plan to spend one hour reading and completing this learning activity.
- Read the entire Clinical Procedure: *Procedural Sedation: Adult*, as well as Addendum 1 and Addendum 2
- Read the Self-Learning Packet
- Complete the online Self-Assessment and evaluation, then register for CME credit and print your certificate of completion
- Swedish Medical Staff Services is automatically notified after you complete this module

Introduction

What is it?

Procedural sedation is a sedation method that produces a minimally depressed level of consciousness in which the patient retains the ability to:

1. Independently and continuously maintain an airway
2. Respond appropriately to physical stimulation and verbal commands

Response to pharmacological agents is highly individual; therefore, all pharmacological agents must be titrated according to the patient's response.

Goals

The goals of moderate procedural sedation are to:

1. Improve patient comfort and tolerance of the procedure
2. Alleviate patient anxiety and apprehension associated with a procedure

Objectives

1. Maintenance of consciousness
2. Minimal variation in vital signs
3. Increased pain threshold
4. Tolerance of the procedure
5. Lack of recall
6. Some degree of "anterograde amnesia"
7. Rapid, safe return of the patient to baseline status

Anterograde amnesia refers to a lack of recall of events *during* the procedure. Retrograde amnesia refers to a lack of recall of events *preceding* the procedure.

Desired Endpoint

The desired endpoint for moderate procedural sedation is a patient who is sedated but can tolerate the procedure.

Adequate sedation is indicated by

1. Visible relaxation
2. Slurred speech
3. Patient report of relaxation when questioned
4. Arousable sleep (the patient may fall asleep, but is easily awakened by spoken commands or light touch)

Desired effects of Procedural Sedation

1. Reduced fear and anxiety before the procedure
2. Intact protective airway reflexes
3. Relaxation and cooperation
4. Easy arousability
5. Minimal changes in vital signs
6. Diminished recall
7. Decreased pain perception

Moderate Procedural Sedation: Terms and Definitions

Terms and Definitions

Moderate sedation analgesia (conscious sedation). Level of sedation 2-1

A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patient airway, and spontaneous ventilation is adequate. Cardiovascular function may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not a purposeful response.

Deep sedation analgesia. Level of sedation 0

A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patient airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Deep sedation requires a post sedation/anesthesia note.

Preparing for Procedural Sedation

Patient Evaluation

Completing the following patient evaluation will determine the patient's health status and therefore the appropriateness of performing the procedure in the clinical facility where it is planned to occur.

You Must Obtain or Update the History and Physical Within 24 Hours Prior to the Procedure.

Review the Medical Record and Medical/Surgical History and Interview the Patient.

Identify factors that increase risk to the patient undergoing a procedure so that adjustments can be made in patient care to increase the probability of a satisfactory outcome. Classify ASA status:

- 1. Healthy patient
- 2. Mild systemic disease, no functional limitations
- 3. Severe systemic disease, definite functional limitations
- 4. Severe systemic disease, constant threat to patient life
- 5. Patient not expected to live beyond 24 hours

Review of Major Organ Systems Including:

1. Cardiac: Coronary artery disease, murmurs, arrhythmia, valve disease, pacemaker, hypertension, congestive heart failure, implanted defibrillators, myocardial infarction, angina, exercise tolerance
2. Pulmonary: Shortness of breath, asthma, wheezing, emphysema, sleep apnea; recent cold, cough, flu, or fever; home oxygen use, smoking dyspnea
3. Endocrine: Diabetes, thyroid, adrenal
4. Kidney/Bladder: Renal insufficiency, dialysis, infections
5. Musculoskeletal: Arthritis, back/neck/joint problems, joint replacement
6. Neurological: Seizures, strokes, headaches, syncope, level of consciousness
7. Hematologic: Bleeding/clotting disorders, anemia, sickle-cell anemia, bleeding
8. Gastrointestinal: Hiatal hernia, reflux, ulcers, bleeding, vomiting
9. Female/Reproductive: Currently pregnant? Possibility of being pregnant?

Surgical History

1. Surgeries, diagnostic procedures
2. Prior anesthetic history

Moderate Procedural Sedation: Preparing for Procedural Sedation

(Patient Evaluation, cont'd)

Current Medications

Medications currently taken provide clues to underlying diseases, potentially harmful drug interactions, as well as medications that will possibly need to be eliminated or modified before the procedure (i.e., ASA, NSAIDs, anticoagulants, insulin)

Perform Airway Assessment

Airway Risks:

1. Capped, loose, or chipped tooth
2. Excessive soft tissue of the chin and neck
3. Dentures
4. Sleep Apnea history
5. Adverse reaction to anesthesia
6. BMI greater than 35

Drug/Other Allergies or Intolerances

Identify patients with any medication or other allergies (latex, iodine, shellfish, tape) or intolerance, and assure avoidance of those medications, items or products pre-, intra-, and post-procedure.

Tobacco, Alcohol, or Substance Use/Abuse

Determine past and present use/abuse for possible impact on patient's care

Physical Exam

Gather sufficient information supplemental to the Medical History information, so that medical personnel involved in care of the patient can provide safe care and quality of care. This should include evaluating the airway:

1. Mouth should open to three finger widths.
2. Neck should have normal flexion and extension without pain or paresthesias.
3. The Mallampati score should be determined.

Class 1: Full visibility of tonsils, uvula and soft palate

Class 2: Visibility of hard and soft palate, upper portion of tonsils and uvula

Class 3: Soft and hard palate and base of the uvula are visible

Class 4: Only Hard Palate visible



Class I: soft palate, uvula, fauces, pillars visible
No difficulty



Class II: soft palate, uvula, fauces visible
No difficulty



Class III: soft palate, base of uvula visible
Moderate difficulty



Class IV: hard palate only visible
Severe difficulty

Patient Teaching

Provide information to the patient/family that maximizes understanding of the procedure before it begins to reduce risk, increase patient compliance and increase the probability of a satisfactory outcome. Use verbal or written methods (or a combination of both), as best fits your patient population and the nature of the information given. Remember to document your teaching.

Procedure Counseling

Diagnostic Procedure:

What typically to expect, and usual length of procedure and recovery.

Admission/Intraoperative/Recovery Process:

Description of physical surroundings, sequence of events, anticipated sights, sounds, smells.

Medication/Sedation:

Expected effects of relaxation/comfort; sensations of light-headedness or dizziness and sleepiness

Personal Instruction:

Where and when to arrive, where to park, what to wear, NPO and medication instructions, and arrangements for a designated driver post-procedure. If history of sleep apnea bring CPAP.

Questions/Concerns of Patient/Family:

Specific concerns/questions of patient and family regarding procedure and post-procedure information.

Informed Consent

Must be obtained and witnessed before sedation is given by the LIP.

Permission obtained from patient to perform a specific test or procedure after the patient has been fully informed about the procedure. **The responsibility for obtaining a patient's informed consent rests with the person performing the procedure.**

Responsibility of the Signature Witness

- The witness confirms the patient was awake, alert, and aware of what he/she was signing
- The witness can answer any questions that are within the scope of the witness's practice.
- The role of witness does not include legal responsibility for disclosing all relevant information to patient
- If the witness observes the patient to be confused about the explanation, he is responsible for documenting the confusion and making sure the patient gets the information from another source

Moderate Procedural Sedation: Preparing for Procedural Sedation

(Patient Teaching, cont'd)

Pre-Procedure Fasting Instructions

Elective Procedures

Because sedatives & analgesics tend to impair airway reflexes in proportion to the degree of sedation/analgesia achieved, the following fasting guidelines should be followed:

Adult Patient

1. Clear liquids only 8 hours prior to patient check-in
2. Nothing by mouth 3 hours prior to procedure

Clear liquids include: water, apple juice, black coffee or tea, carbonated beverages, broth, Jell-O, popsicles (no red liquids).

Not Allowed: coffee/tea with milk or cream, alcoholic beverages

Urgent/Emergent/Suspected Delayed Gastric Emptying

In urgent situations, observation of NPO guidelines may not be possible. In these situations, the potential for pulmonary aspiration should be considered in determining use of procedural sedation medications.

Unanticipated Need for Sedation/Analgesia

Occasionally, patients manifest the need for sedation/analgesia during procedures that are routinely performed without sedation/analgesia. In these cases, the physician should assess the patient and weigh the risks and benefits of proceeding. The potential for pulmonary aspiration of gastric contents should be considered in determining whether or not to proceed. Patients given sedation/analgesia should be evaluated, monitored, and recovered and discharged as outlined in the SMC Procedural Sedation Protocol and Flow Sheet

Initial Post-Procedure Care Instructions

Patients who are to sign instruction sheets as validation of understanding must sign them prior to receiving any procedural sedation medications.

Discharge planning is most effective if begun in the pre-admission period and reinforced with written instructional material.

Specific instructions appropriate for **every** patient who will be undergoing Procedure Sedation include:

- Do not drive for the rest of the day
- Do not engage in other activities requiring judgment or coordination for the rest of the day
- Do not consume any alcoholic beverages for the rest of the day
- Do not sign any legal documents for the rest of the day
- Have a responsible person available to assist you until you are fully awake
- Conditions under which immediate emergency care should be sought

Additional discharge instructions dependent upon the procedure might include information about:

- Activity restrictions/resumption
- Pain control/symptom relief
- Diet
- Follow-up visit
- Emergency contact of physicians

Admission and Documentation

Insure Consent and Chart are Complete

It is essential that qualified clinical staff have knowledge of the patient's condition, as well as the patient's knowledge of the procedure.

Why?

1. To obtain additional patient medical/surgical history to assist team members in providing quality, safe care.
2. To document care provided in a sequential, consistent matter that:
 - a) Provides ready reference in reviewing patient response and interventions taken
 - b) Provides legal documentation for care provided to patient.

Pre-Procedure Assessment

- a) Date
- b) Licensed Independent Practitioner Name (LIP)
- c) Procedure
- d) History/Physical Exam * Including airway assessment and BMI
- e) ASA Classification *
- f) Plan for Sedation Including Target Level *
- g) Medication Orders *
- h) LIP Signature *

Informed Consent for Procedure

- a) Patient Name *
- b) Name of physician performing the procedure *
- c) Detailed name of procedure *
- d) Date and time of Signature*
- e) Patient or Guardian
- f) Witness Signature

*Must be completed by the Licensed Independent Practitioner

Care of the Patient During Sedation

Primary Responsibility in Patient Management

- 1) **Safety pause and procedural verification:** The safety pause is the moment immediately prior to sedation or incision when the proceduralist and sedation team states the patient's name, procedure, and when applicable side/site marked, and receives verbal agreement from members of the procedure team.
- 2) Administration of medication for moderate procedural sedation (by physician, RN, or licensed provider under direct supervision of the attending Physician)
- 3) Observation of the patient for desired effect of medications
- 4) Monitoring the patient throughout the procedure:
Because the LIP may be focused on the procedure itself, the nurse should be continuously present during the sedation of the patient and the procedure. The qualified licensed staff's primary role is to monitor the patient. However, the individual may assist with the interruptible tasks of short duration, provided that monitoring is maintained. The ultimate goal of monitoring is the early detection and correction of adverse effects. Continuous monitoring is critical, because the medications for moderate procedural sedation can cause rapid adverse physiologic changes

In addition, the designated observer should:

- Appraise the LIP of the patient's condition
 - Support the patient by providing emotional support and assure a response to needs
- 5) Procedural sedation and its management is the responsibility of the whole team. However, the final responsibility lies with the LIP. The credentialed LIP needs to be present during the procedure and administration of the medications.

Monitoring the Patient

- 1) Insure that continuous IV access is maintained
- 2) Monitor the patient's
 - Pulse
 - Respiratory rate/effort (using observation and/or auscultation)
 - Cardiac rhythm (required if patient was monitored prior to procedure)
 - Sedation level (0-3)
 - Blood pressure (NIBP)
 - Pain level (1-10)/or Colorado Behavioral Numerical Pain scale for sedated patients (CBNP)
 - Oxygen saturation via pulse oximetry
 - Consider end-tidal CO₂ monitoring
- 3) Assess level of consciousness
Monitoring patient's responsiveness to verbal commands and/or tactile stimuli. Other indicators of sedation include slurred speech, visible relaxation.

Moderate Procedural Sedation: Care of the Patient During Sedation

(Monitoring the Patient, cont'd)

4) Assess patient's tolerance of pain:

Indications that a patient may need more sedation/analgesia include hypertension, tachycardia, patient report of pain/discomfort, stressed facial expression, restlessness, or signs of awakening (e.g., fully opened eyes, talking, moaning, etc), **with** stable respiratory and cardiovascular status.

5) Observe for and report any complications from Procedural Sedation and be prepared to institute rescue measures:

- a. SaO₂ hemodynamic instability, restlessness, pallor, flushing, cyanosis, diaphoresis, nausea, palpitations, and all others, as you deem worthy of note.
- b. Airway Obstruction or Respiratory Depression
 - Airway management always comes first. Be sure the patient's airway is patent by positioning the head appropriately. Suction or insert an airway only if necessary
 - Monitor SaO₂
 - Ask patient to take deep breaths, use verbal or gentle tactile stimulation
 - Administer supplemental O₂ per order/by protocol
 - Check RR and depth by observation and/or auscultation
 - Manually ventilate if necessary. Because dusky skin or nail-bed color are late signs of respiratory depression, it is important to monitor and intervene before these signs occur.
- c. Excessive Sedation
 - Maintain the ABC's (airway, breathing and circulation)
 - Prepare administer reversal agents. The treatment depends upon the drug(s) used to achieve procedural sedation
 - Monitor respiratory status closely until stable
 - Manually ventilate if necessary. Because dusky skin or nail-bed color are late signs of respiratory depression, it is important to monitor and intervene before these signs occur.
- d. Cardiac Arrhythmias

Most common are bradycardia (secondary to hypoxia, or to vagal stimulation from procedure) and tachycardia (secondary to pain, anxiety, hypoxemia, or hypovolemia). More serious are PVC's and atrial arrhythmias (which may be caused by hypoxemia). Make sure airway is patent

 - Monitor pulse oximetry
 - Administer or increase oxygen
 - Administer fluids
 - Administer anti-arrhythmia drugs, per ACLS or as ordered
- e. Hypotension

A drop of 20% below normal, the pre-procedure/treatment baseline or at a level where the patient is symptomatic. Possible causes include: Pre-existing problem, hypovolemia, and response to medication

 - Support respiratory status
 - Fluid or vasopressors, as appropriate
 - Continue to assess **BP** every 1-5 minutes
- f. Increase in BP during procedure

May be the result of pain or stress of the procedure. Need to re-evaluate Additional sedation may be indicated.

Undesirable Effects of Sedation

As with most invasive measures, there are possible undesirable effects of procedural sedation

- Non-arousable sleep
- Airway obstruction
- Apnea
- Cardiac arrhythmia
- Respiratory insufficiency
- Thrombophlebitis
- Injection site pain
- Nystagmus (may be normal with large doses of diazepam)
- Allergic reactions (e.g., rash, redness, itching, hives, edema, hypotension, syncope, bronchoconstriction, or respiratory distress)
- Paradoxical response

Paradoxical Response

A paradoxical response manifests as non-cooperation, mental confusion, agitation or combativeness as additional sedative medication is administered. It is seen most often in alcoholic patients and/or IV drug abusers, who have a higher tolerance for the effects of sedative drugs. Such responses can also result from inadequate or excessive dosing or improper administration of the drug. Consideration should also be given to the possibility of cerebral hypoxia or a true paradoxical reaction.

Prompt recognition of a paradoxical reaction is important to avoid the complications of every medication. The paradoxical response should not be interpreted as a need for additional sedation. The sedative dose on board should be allowed to take effect before making further attempts to initiate the procedure on an agitated, uncooperative patient. If necessary, intravenous flumazenil (which reverses the effects of benzodiazepine-induced sedation) can be administered. The procedure should continue only when the patient becomes cooperative and exhibits other signs of adequate conscious sedation

Use of Reversal Agents

The routine use of reversal agents in procedural sedation is not recommended. The sedation may often outlast the reversal agent, therefore this could result in an adverse outcome. Reversal agents should only be used where there is an adverse effect of the procedural sedation or of the procedure itself.

Hospital Monitoring of Procedural Sedation Outcomes

In order to keep procedural sedation as safe as possible, adverse outcomes during procedural sedation will be monitored and reviewed by the SMC Procedural Sedation Committee.

Review of Sedative and Analgesic Agents

The choice of agent for sedation/analgesia should be dictated by the needs of the patient, his/her medical condition, the requirements of the procedure and the expertise of the practitioner. No single drug or drug dosage can (or should) be used in all situations. Remember that the elderly and frail may be more sensitive to medications to start with the lower initial dose and slowly increase the dose as needed.

Review the Definition of Moderate Sedation

Moderate sedation/analgesia (procedural sedation). Level of sedation 2-1. A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

An “ideal agent” would...

1. Exhibit a rapid and predictable onset of action following administration.
2. Have a predictable dose-effect relationship, uniform and narrow dose response, a wide therapeutic range, and would allow for a quick recovery.
3. Feature minimal respiratory or cardiovascular depressant effects, and minimal excitatory effects on the central nervous system.
4. Have predictable anxiolysis and amnesia with no post-sedation confusion, a lack of accumulation and a low incidence of post-procedure nausea or vomiting.
5. Be soluble in water, stable in solution and non-irritating on injection, and be physically compatible with other agents.
6. Possess some analgesic properties and have no potential for allergic or hypersensitive reactions.
7. Have a reversal agent available that is safe and predictable.

Therefore...

In attempting to achieve these goals, sometimes sedative agents from two or more classes are used. This practice takes advantage of the synergy between classes of sedative agents, such as the combination of effects from opioids and benzodiazepines.

A sedative alone may be appropriate for some patients undergoing non-painful procedures, while other patients may require an opioid analgesic. Some drugs, particularly the benzodiazepines, show tremendous variability in patient response. Therefore, individual titration of sedative and analgesic agents is essential.

BENZODIAZEPINES

- Diazepam
- Midazolam
- Lorazepam

As a class, the benzodiazepines act by enhancing the inhibitory effects of gamma-aminobutyric (GABA) on chloride channels in neurons at all levels of neuraxis. This yields the effects of anxiolysis, sedation, hypnosis, amnesia, muscle relaxation, and anti-convulsant activity. The variety of effects and the extent of the effects vary according to the particular agent and the dose. Although large doses of benzodiazepines are required to cause respiratory depression, combining these agents with opioids during procedural sedation procedures potentiates the risk of respiratory depression.

Extreme care should be used in patients who are chronically on benzodiazepines and need reversal from over-sedation during procedural sedation. Flumazenil in those patients can lead to intractable seizures.

DIAZEPAM (Valium)

Diazepam is an agent that is poorly soluble in water, and therefore is solubilized in propylene glycol, ethyl alcohol, benzoic acid, and benzyl alcohol. This preparation, when administered intravenously, is notorious for causing pain and venous irritation. Dilution of diazepam in water or saline causes cloudiness, but does not affect potency.

Onset of action (min): Less than 2 minutes.

Peak effect (min): 3-4 minutes; duration of sedation 15-60 minutes; residual effects may be seen for up to 4 hours.

Side-Effects: Diazepam can produce respiratory depression, hypotension, excessive sedation, and apnea, especially in the presence of opioids. Liver and renal disease can cause accumulation of the drug and its metabolites, causing prolonged sedation. Accumulation effect is also likely to occur in elderly & in patients with congestive heart failure.

Recommended Doses: Usual dose to achieve anxiolysis and retrograde amnesia is 2-5 mg. Age 18-60 years: 2.5 mg IV over 3-5 minutes to maximum of 0.2 mg/kg if opioids not administered. Age over 60 &/or poor risk: 1.5 mg IV over 3-5 minutes to maximum of 0.1 mg/kg if opioids not administered.

Reversal Agent (Flumazenil): For reversal of conscious sedation from benzodiazepine (Flumazenil), 0.2 mg IV over 15 seconds may be given. After waiting 45 seconds, an additional 0.2 mg may be given and repeated at 60-second intervals up to 1 mg. If re-sedation occurs, re-titrate Flumazenil in 0.2 mg/minute increments, to a total of 1 mg every 20 minutes, not to exceed 3.0 mg over one hour. Patients should be watched for re-sedation for at least 1 hour after the last dose of Flumazenil.

MIDAZOLAM (Versed)

This agent is one of the most widely used agents in procedures requiring procedural sedation (usually in combination with fentanyl as the opioid). It provides profound procedural amnesia

Moderate Procedural Sedation: Review of Sedative and Analgesic Agents

and sedation. Midazolam is water-soluble, so it is well-tolerated when administered intravenously.

Midazolam is approximately three-times as potent as diazepam. The elimination half-life may be doubled in the elderly, reflecting decreased hepatic blood flow and enzyme activity.

Onset of Action: 30 seconds to 1 minute.

Peak effect (min): 3-5 minutes; duration of sedation is 15-80 minutes. Anterograde amnesia occurs within 1-5 minutes & persists for 20-40 minutes.

Side-Effects: Midazolam can produce respiratory depression, hypotension, excessive sedation, and apnea, especially in the presence of opioids in the elderly. Midazolam is capable of producing all levels of CNS depression from mild sedation to respiratory depression to coma.

Recommended Doses: Doses greater than 5 mg should be administered by physician. Age 18-60 years: 1-5 mg IV over 2 minutes; titrate in 1 mg increments to maximum total dose of up to 0.2 mg/kg when used without an opioid; decrease dose by 30% when given with an opioid. Age over 60 years &/or poor risk: 0.5-1.5 mg IV over 2-3 minutes to maximum total dose of up to 0.1 mg/kg when used without an opioid; decrease dose 33-50% when given with an opioid.

Reversal Agent (Flumazenil): For reversal of conscious sedation from benzodiazepine (Flumazenil), 0.2 mg IV over 15 seconds may be given. After waiting 45 seconds, an additional 0.2 mg may be given and repeated at 60-second intervals up to 1 mg. If re-sedation occurs, re-titrate Flumazenil in 0.2 mg/minute increments, to a total of 1 mg every 20 minutes, not to exceed 3.0 mg over one hour. Patients should be watched for re-sedation for at least 1 hour after the last dose of Flumazenil.

LORAZEPAM (Ativan)

Lorazepam is a potent amnesic, and has a significantly slower onset and longer duration of action than either midazolam or diazepam. The slow onset and long duration of action limit its use for intravenous sedation in the ambulatory procedural areas.

Onset of Action: 1.5 minutes.

Peak effect (min): 15-20 minutes; duration of sedation is 6-10 hours.

Side-Effects: Respiratory depression in elderly or when combined with opioids. Hypotension when combined with opioids.

Recommended Doses: Age 18-60 years: 1-2 mg IV over 1-2 minutes to maximum of 0.04 mg/kg. Age over 60 &/or poor risk: 0.5-1 mg IV; give in 0.5 mg increments every 5 minutes to maximum of 0.03 mg/kg. Decrease dose by 30% when given with opioids.

Reversal Agent: For reversal of conscious sedation from benzodiazepine, 0.2 mg IV over 15 seconds may be given. After waiting 45 seconds, an additional 0.2 mg may be given and repeated at 60-second intervals up to 1 mg. If re-sedation occurs, re-titrate Flumazenil in 0.2 mg/minute increments, to a total of 1 mg every 20 minutes, not to exceed 3.0 mg over one hour. Patients should be watched for re-sedation for at least 1 hour after the last dose of Flumazenil.

BENZODIAZEPINE ANTAGONISTS

FLUMAZENIL (Romazicon)

Flumazenil is a competitive antagonist with a high affinity for benzodiazepine receptors. Flumazenil's elimination half-life is approximately one hour. Although effective as an antagonist, its action is sometimes thwarted by the longer half-life of the agent it is meant to oppose. The efficacy of Flumazenil depends on the agent and dose of benzodiazepine it is meant to oppose. Administration of Flumazenil in patients with a considerable tissue level of benzodiazepine can cause reversal of the effects, followed by a period of re-obtundation after the effects of the reversal have worn off. For this reason, the use of Flumazenil requires an extended observation period before the patient can be declared no longer under the influence of the benzodiazepine.

Flumazenil may precipitate seizures in patients with convulsive disorders, CNS pathology, benzodiazepine tolerance/dependent, or multiple-drug overdose (especially tricyclic antidepressants). Adequate oxygenation and ventilation should be ensured prior to administration of Flumazenil. In situations of suspected benzodiazepine overdose, the airway should be secured prior to administration of Flumazenil. Flumazenil is an adjuvant to – not a substitute for – proper airway management.

Adverse Side-Effects: Nausea and vomiting, dizziness, pain on injection, agitation/anxiety, re-sedation and convulsions.

OPIATES

All of the opiates interact with the opiate receptors in the central nervous system to produce analgesia and other side-effects. The use of opioids should be reserved for procedures that are painful. Opioids are not indicated for amnesia or anxiolysis. The three major designations of opioid receptors are mu, kappa, and delta. These receptors are connected with analgesia and each as identified subtypes that are respectively connected with such opiate side-effects as respiratory depression, constipation, physical dependence and sedation. The differences in onset and duration of the opiates can be attributed to their affinity for the receptors, their lipid-solubility (reflecting their ability to cross the blood-brain barrier), half-life and the presence or absence of active metabolite. Side-effects of all these agents increase with the dose and the rate of administration. All opiates are metabolized in the liver, with the metabolites largely excreted by the kidneys.

Remember the respiratory depression effect of opiates when combining them with benzodiazepines.

FENTANYL

Fentanyl is more lipophilic than morphine and crosses the blood-brain barrier faster. Because the opioid receptors are situated primarily in spinal and supraspinal sites, the rapidity with which the drug passes from the circulation into the central nervous system dictates how rapidly analgesic effect can be achieved. Onset is usually within 30 seconds. Lipid-solubility of this drug also accounts for its short action, via re-distribution away from the central nervous system to peripheral lipid stores. A dose of 100 mcg (2 ml) is approximately equivalent in analgesic activity to 10 mg of morphine or 75 mg of meperidine.

Onset of Action: Within 1 minute.

Moderate Procedural Sedation: Review of Sedative and Analgesic Agents

Peak effect (min): Peak analgesia within 1-3 minutes; duration of analgesia 30-60 minutes after a single dose of up to 100 mcg.

Side-Effects: Rapid IV push of more than 100 mcg may cause chest wall muscle rigidity. Fentanyl can cause ventilatory depression, apnea, sedation, hypotension, nausea, vomiting, cardiovascular depression and euphoria.

Recommended Doses: Age 18-60 years: 25-50 mcg over 1-2 minutes to max of 100 mcg/hr. Age over 60 &/or poor risk: 12.5 mcg IV over 1-2 minutes to max of 50 mcg/hr.

Reversal Agent: Naloxone (Narcan) 1 to 5 mcg/kg, depending upon the urgency of the situation. In emergency situations, one amp (400 mcg) can be given IV. Keep in mind that the duration of naloxone is shorter than the opioid's duration, so prolonged observation is necessary after giving naloxone, and repeat doses may be necessary.

MORPHINE

Morphine is a prototypical opioid analgesic agent to which all other opioids are compared. In humans, morphine produces analgesia, euphoria, sedation, and diminished ability to concentrate. Other sensations include nausea, a feeling of body warmth, heaviness of extremities, dryness of the mouth, and pruritus, especially around the nose. Morphine is poorly soluble in lipids, limiting its access through the blood-brain barrier. Morphine has a relatively slow onset and long duration of action, limiting its use in procedural sedation.

Onset of Action: Within 1-3 minutes.

Peak effect (min): Peak analgesia occurs within 20 minutes and may last up to 7 hours. Maximal respiratory depression usually occurs within 7 minutes.

Side-Effects: Morphine can cause ventilatory depression, apnea, sedation, hypotension, nausea, vomiting, chest-wall rigidity, cardiovascular depression and euphoria.

Recommended Doses: Age 18-60 years: 1-2 mg IV over 2 minutes every 5 minutes to maximum of 0.1 mg/kg. Age over 60 &/or poor risk: 0.5-1 mg IV over 2 minutes every 5 minutes to maximum of 7.5 mg.

Reversal Agent: Naloxone (Narcan) 1 to 5 mcg/kg, depending upon the urgency of the situation. In emergency situations, one amp (400 mcg) can be given IV. Keep in mind that the duration of naloxone is shorter than the opioid's duration, so prolonged observation is necessary after giving naloxone, and repeat doses may be necessary.

MEPERIDINE

Meperidine has been removed from the Swedish Medical Center formulary except for the use postoperatively with post anesthesia shivering.

OPIOID ANTAGONISTS

NALOXONE

Naloxone, an opioid antagonist, has affinity for all three of the opioid receptors. Because its half-life is similar to that of the agents it antagonizes, often one dose or a series of doses given 20 minutes apart is sufficient to reverse the central nervous system and respiratory depression of

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the opioid. Antagonism of opioid-induced ventilatory depression is accompanied by an inevitable reversal of analgesia. It may be possible, however, to titrate the dose of naloxone such that depression of ventilation is partially but acceptably antagonized, so as to maintain partial analgesia.

Side-Effects: Nausea and vomiting appear to be closely related to the dose and speed of injection of naloxone. Administration of naloxone slowly, over 2-3 minutes, rather than as a bolus, seems to reduce the incidence of nausea and vomiting. Cardiovascular stimulation following administration of naloxone manifests as increased sympathetic nervous system activity, presumably reflecting the abrupt reversal of analgesia and the sudden percept of pulmonary edema, and cardiac dysrhythmia. Ventricular fibrillation has even occurred following intravenous administration of naloxone.

Profolol and Etomidate

These medications are **not** appropriate or approved for use in Procedural Sedation. These drugs may easily lead to deep sedation / anesthesia.

Next Steps:

Ensure you have read the following documents in their entirety (available at: www.swedish.org/proceduralsedation):

- Self Learning Packet
- *Procedural Sedation: Adult Clinical Procedure*
- Addendum 1 to *Procedural Sedation: Adult Clinical Procedure*
- Addendum 2 to *Procedural Sedation: Adult Clinical Procedure*

Please complete the online Self-Assessment at www.swedish.org/proceduralsedation. You will then be directed to complete an evaluation, register for CME credit and print your certificate of completion.

Please note: Swedish Medical Staff Services is automatically notified that you completed this module after you print your certificate.